



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

May 7, 2015

Ni Hau Industrial Co., Ltd.  
Ms. Lyn Chiu  
Sales Manager  
No. 15, Alley 125, Lane 318, Section 2, An Ho Road  
Tainan City, Taiwan 70967

Re: K142717

Trade/Device Name: Cat Contact Lens Case, Sunglasses Contact Lens Case, 1st Contact Lens Case, Geeky Eye Contact Lens Case

Regulation Number: 21 CFR 886.5928

Regulation Name: Soft (Hydrophilic) Contact Lens Care Products

Regulatory Class: Class II

Product Code: LRX

Dated: April 10, 2015

Received: April 13, 2015

Dear Ms. Chiu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"

(21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 **Kesia Y. Alexander -A**

for Malvina B. Eydelman, MD  
Director  
Division of Ophthalmic and Ear, Nose,  
and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K142717

Device Name

Cat Contact Lens Case / Sunglasses Contact Lens Case

1st Contact Lens Case

Geeky Eyes Contact Lens Case

Indications for Use (Describe)

For storage of soft (hydrophilic), hard, and rigid gas permeable contact lenses during chemical disinfection. Use for storage during chemical disinfections only. DO NOT USE WITH HEAT.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Joseph C. Hutter -S

Digitally signed by Joseph C. Hutter -S  
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300106195, cn=Joseph C. Hutter -S  
Date: 2015.05.05 10:56:22 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*



## Ni Hau Industrial Co., Ltd.

No. 15, Alley 125, Lane 318, Section 2, An Ho Rd., Tainan City, Taiwan

TEL : +886- 6- 355- 7000

FAX : +886- 6- 355- 9000 、 355-0297

E-MAIL : [lyn@ni-hau.com.tw](mailto:lyn@ni-hau.com.tw),

---

### 510(k) Summary

<b>(1) 510(k) Proprietary Details</b>	
Date of Summary:	MAY 05, 2015
Company:	Ni Hau Industrial Co., Ltd.
Address:	No. 15, Alley 125, Lane 318, Section 2, An Ho Road, Tainan City, TAIWAN. Postal Code: 70967
Telephone:	(886) 6-355 7000 Extension 64
Fax:	(886) 6 – 355 9000
Email:	<a href="mailto:lyn@ni-hau.com.tw">lyn@ni-hau.com.tw</a>
Contact Person:	Ms. Lyn Chiu

<b>(2) 510(k) Device Details:</b>	
Device Name:	Cat Contact Lens Case Sunglasses Contact Lens Case 1st Contact Lens Case Geeky Eyes Contact Lens Case
Device Model #:	K-489 (Cat) K-488 (Sunglasses) K-506 (1 <sup>st</sup> Contact) K-507 (Geeky Eyes)
Device:	Case, Contact Lens
Classification Description:	Soft (hydrophilic) contact lens care products.
Review Panel:	Ophthalmic
Product Code:	LRX
Submission Type:	510(k)
Regulation Number:	886.5928
Device Class:	II



## Ni Hau Industrial Co., Ltd.

No. 15, Alley 125, Lane 318, Section 2, An Ho Rd., Tainan City, Taiwan

TEL : +886- 6- 355- 7000

FAX : +886- 6- 355- 9000 、 355-0297

E-MAIL : [lyn@ni-hau.com.tw](mailto:lyn@ni-hau.com.tw),

### (3) Predicate Device:

Device Name:	Owl Contact Lens Case Dog Contact Lens Case
Device Trade Name:	Owl Contact Lens Case Dog Contact Lens Case
Device Model Number:	MG00-A (Owl) MG37-A (Dog)
Classification Product Code:	LRX
Device Class:	II
510(k) Submitter/ Holder	NINGBO LISHUNDA ELECTRONICS CO., LTD.
510(k) Number	K130930

### (4) Device Description:

The contact lens cases in submission are intended to be used to store soft (hydrophilic) and hard contact lenses during chemical disinfection only. These are not to be used in heat disinfection.

There are 2 parts to each contact lens case, the main body/base with two wells, and two screw-on lids. In order to store contact lenses with disinfection solution, the wells for storage need to be leak-proof, which is designed so by the screw construction of the lids.

The plastic that is used in all four contact lens cases is Acrylonitrile Butadene Styrene (Product Name: Polylac ® PA-707, manufactured by Chi Mei Corporation, please refer MSDS attached: Attachment 1), which is a durable plastic that is insoluble in water and can be used for at least two months continuous use.

The cat contact lens case is black, with white printed on the lids. The color pigment used in the case is PLASBLAK® UN2014 (Supplier: Cabot Plastics, please refer MSDS attached: Attachment 2). This pigment is insoluble in water.



## Ni Hau Industrial Co., Ltd.

No. 15, Alley 125, Lane 318, Section 2, An Ho Rd., Tainan City, Taiwan

TEL : +886- 6- 355- 7000

FAX : +886- 6- 355- 9000 、 355-0297

E-MAIL : [lyn@ni-hau.com.tw](mailto:lyn@ni-hau.com.tw),

---

The sunglasses contact lens case is white, with black labels on the lids. The color pigment used in the case is DuPont™ Titanium Dioxide Pigment - Plastics Grade/Type : R-350 (Supplier: DuPont, please refer MSDS attached: Attachment 3). This pigment is insoluble in water.

The 1<sup>st</sup> contact lens case is green, with clear uncolored lids. There are 2 color pigments used in the green body (1) PV Fast Green GNX (Supplier: Clariant Chemicals (India) Limited, please refer MSDS attached: Attachment 4) and (2) MACROLEX Yellow G Granulate (Supplier: Bayer AG, please refer MSDS attached: Attachment 5). These pigments are insoluble in water.

The Geeky eyes contact lens case is red with black glasses. The color pigment used in the red case is 13575 Orange Color Powder (Supplier: Summit Color Co., Ltd., please refer MSDS attached: Attachment 6). This pigment is insoluble in water.

The individual well capacity of each contact lens are: cat contact lens case 2.8ml, sunglasses contact lens case 2.5ml, 1<sup>st</sup> contact lens case 3ml, geeky eyes contact lens case 2.8ml. The capacities aforementioned are sufficient for a contact lens to be fully soaked in the disinfection liquid.

At the base of the cat contact lens case and the sunglasses contact lens case, in each well there is L and R embossed to help users differentiate the left and right lenses. The geeky eyes contact lens case also has the L and R markings on the side of the casing outer. The 1<sup>st</sup> contact lens case does not have L and R markings on it as the two wells are situated one above and one below the disc so it is unlikely to mix up the two wells during use.

Through use, the material of the contact lens case may come into contact with the user's eyes indirectly. The user will need to put contact lenses with chemical disinfecting liquid into the contact lens case for storage. Therefore we have used a plastic material and colorants that are insoluble in water so that it will not come in contact with one's eyes.

These contact lens cases are intended for the storage of soft (hydrophilic) and



## Ni Hau Industrial Co., Ltd.

No. 15, Alley 125, Lane 318, Section 2, An Ho Rd., Tainan City, Taiwan

TEL : +886- 6- 355- 7000

FAX : +886- 6- 355- 9000 、 355-0297

E-MAIL : lyn@ni-hau.com.tw,

---

hard contact lenses. The case should ensure the fluids contained do not leak. These cases are for the storage of chemical disinfecting fluids with contact lenses only, they are not to be used in heat disinfection. These are not sold sterile, so the packaging should have instructions written on them to "Rinse the case thoroughly with clean solution before use". It is recommended to replace the contact lens case at least every 3 months.

### (5) Indications For Use

For storage of soft (hydrophilic), hard, and rigid gas permeable contact lenses during chemical disinfection. Use for storage during chemical disinfections only.  
DO NOT USE WITH HEAT.

### (6) Comparison of Devices in Application & Substantially Equivalent Predicate

#### Device:

	The Device in Submission	Substantially Equivalent Predicate Device
Device Name	Cat Contact Lens Case Sunglasses Contact Lens Case 1st Contact Lens Case Geeky Eyes Contact Lens Case	OWL CONTACT LENS CASES DOG CONTACT LENS CASES
Device Model #:	K-489 (Cat) K-488 (Sunglasses) K-506 (1 <sup>st</sup> Contact) K-507 (Geeky)	MG00-A (Owl) MG37-A (Dog)
Device Appearance	 	



## Ni Hau Industrial Co., Ltd.

No. 15, Alley 125, Lane 318, Section 2, An Ho Rd., Tainan City, Taiwan

TEL : +886- 6- 355- 7000

FAX : +886- 6- 355- 9000 、 355-0297

E-MAIL : lyn@ni-hau.com.tw,

Case Dimension	Cat: 65 x 37 x 14mm Sunglasses: 71 x 31 x 14mm 1st Contact: 60 x 39.6 mm Geeky eyes: 80 x 32 x 21mm	Owl: 71 x 38.5 x 17mm Dog: 69.5 x 38 x 14mm
Single Well Capacity Volume	Cat: 3ml Sunglasses: 2.5ml 1st Contact: 3ml Geeky eyes: 2.8ml	Owl: 5.5ml Dog: 4.8ml
Device Material	All 4: (ABS) Acrylonitrile Butadene Styrene	Both: (ABS) Acrylonitrile Butadene Styrene
Device Construction	All 4: Shaped base with two wells to hold the fluid and two screw lids for the Left and Right eyes of contact lenses.	Both: Shaped base with two wells and two screw lids
Device Intended Use	All 4: To hold soft and hard contact lenses. For storing chemical disinfecting fluid only.	Both: To hold soft and hard contact lenses. For storing chemical disinfecting fluid only.
Biocompatibility	PASS the following test: Cytotoxicity (ISO 10993-5) Eye Irritation (ISO 10993-10) Systematic Toxicity (ISO 10993-11)	PASS the following test: Cytotoxicity (ISO 10993-5) Eye Irritation (ISO 10993-10) Systematic Toxicity (ISO 10993-11)
Sterilization	Not sold sterile	Not sold sterile



## **Ni Hau Industrial Co., Ltd.**

**No. 15, Alley 125, Lane 318, Section 2, An Ho Rd., Tainan City, Taiwan**

**TEL : +886- 6- 355- 7000**

**FAX : +886- 6- 355- 9000 、 355-0297**

**E-MAIL : [lyn@ni-hau.com.tw](mailto:lyn@ni-hau.com.tw),**

---

Since the construction, materials and specifications of the devices in submission are very similar to the substantially predicate devices, which have been safely distributed in the USA market, we can conclude that our Cat Contact Lens Case, Sunglasses Contact Lens Case, 1st Contact Lens Case, and Geeky Eye Contact Lens Case are also safe to be distributed in the U.S.A.